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Subpart E—Control of Components

§ 820.80 Components.

Components used in manufacturing shall be received, stored, and handled in a manner designed to prevent damage, mixup, contamination, and other adverse effects. Components shall be quarantined prior to acceptance or clearly identified as not yet accepted.

(a) *Acceptance of components.* There shall be a written procedure for acceptance of components. A designated individual(s) shall accept or reject components. A record shall be maintained of component acceptance and rejection. Upon receipt, each shipping container of components shall be visually examined for damage. Where deviations from component specifications could result in the device being unfit for its intended use, components shall be inspected, sampled, and tested for conformance to specifications.

(b) *Storage and handling of components.* If the quality or fitness for use of components deteriorates over time, the components shall be stored in a manner to facilitate proper stock rotation. Component control numbers or other identifications shall be easily viewable. All obsolete, rejected, or deteriorated components shall be clearly identified and segregated from accepted components. Records shall be maintained of the disposition of all obsolete, rejected, or deteriorated components.

§ 820.81 Critical devices, components.

In addition to the requirements of § 820.80, the following requirements apply to critical devices:

(a) *Acceptance of critical components.* There shall be written procedures for the accepting, sampling, testing, and inspecting of all lots of critical components to assure that critical components conform to specifications. The number of units sampled from each lot of critical components shall be based upon an acceptable statistical rationale, the past quality history of the supplier, and the quantity needed for analysis and reserve. Each lot of critical components shall be identified with a control number(s) upon receipt. The percentage of defective critical components for each lot and the percentage of lots rejected shall be recorded and identified by supplier name.

(b) *Critical component supplier agreement.* Where possible, the manufacturer shall secure from the critical component supplier a written agreement whereby the supplier agrees to notify the manufacturer of any proposed change in a critical component. Where such an agreement exists, the manufacturer shall not accept such a change until the manufacturer has determined the impact of the change on the finished device.

Subpart F—Production and Process Controls

§ 820.100 Manufacturing specifications and processes.

Written manufacturing specifications and processing procedures shall be established, implemented, and controlled to assure that the device conforms to its original design or any approved changes in that design.

(a) *Specification controls.* (1) Procedures for specification control measures shall be established to assure that the design basis for the device, components, and packaging is correctly translated into approved specifications.

(2) Specification changes shall be subject to controls as stringent as those applied to the original design specifications of the device. Such changes shall be approved and documented by a designated individual(s) and shall include the approval date and the date the change becomes effective.

(b) *Processing controls.* (1) Where deviations from device specifications could occur as a result of the manufacturing process itself, there shall be written procedures describing any processing controls necessary to assure conformance to specifications.

(2) All processing control operations shall be conducted in a manner designed to assure that the device conforms to applicable specifications.

(3) There shall be a formal approval procedure for any change in the manufacturing process of a device. Any approved change shall be communicated to appropriate personnel in a timely manner.

§ 820.101 Critical devices, manufacturing specifications, and processes.

In addition to the requirements of § 820.100, the following requirements apply to critical devices:

(a) *Critical operation performance.* Any critical operation shall be performed by a suitable designated individual(s) or suitable equipment and shall be verified.

(b) *Record of critical operation.* Any individual responsible for the performance of a critical operation shall record or reference that operation in the device history record as required in § 820.185.

§ 820.115 Reprocessing of devices or components.

(a) Reprocessing procedures shall be established, implemented, and controlled to assure that the reprocessed device or component meets the original, or subsequently modified and approved, specifications.

(b) Any device rejected during finished device inspection and later reprocessed shall be subject to another complete final inspection for any characteristic of the device which may be adversely affected by such reprocessing.

§ 820.116 Critical devices, reprocessing of devices or components.

In addition to the requirements of § 820.115, the following requirements apply to critical devices:

(a) *Reprocessing procedures.* There shall be written procedures for any reprocessing associated with the production of a critical device or component. These procedures shall prescribe the equipment to be used in reprocessing and shall include any special quality assurance methods or tests. The procedures shall be designed so that the reprocessed device or component meets the original, or subsequently modified and approved, specifications. The procedures shall be designed to prevent adulteration, e.g., because of material, structural, or molecular change in the device or component due to reprocessing. Special care shall be taken to assure that the device or component to be reprocessed is clearly identified and separated from like devices or components not to be reprocessed. When there is constant reprocessing of a device or component, a determination of the effect of the reprocessing upon the device or component shall be made and documented. There shall be a formal approval procedure for instituting a new, or altering an approved, reprocessing procedure.

(b) *Reprocessing control.* Any critical device or component subject to reprocessing procedures shall conform to the original, or subsequently modified and approved, specifications. Written testing and sampling procedures to assure such comformity shall be contained or referenced in the device master record. Any prior quality assurance check shall be repeated on the reprocessed device or component if the reprocessing could adversely affect any performance characteristic previously inspected.

Subpart G—Packaging and Labeling Control

§ 820.120 Device labeling.

There shall be adequate controls to maintain labeling integrity and to prevent labeling mixups.

(a) *Label integrity.* Labels shall be designed, printed, and applied so as to remain legible during the customary conditions of processing, storage, handling, distribution, and use. Labels and other labeling shall not be released to inventory until a designated individual has proofread samples of the labeling for accuracy.

(b) *Separation of operations.* Each labeling or packaging operation shall be separated physically or spatially in a manner designed to prevent mixups.

(c) *Area inspection.* Prior to the implementation of any labeling or packaging operation, there shall be an inspection of the area where the operation is to occur by a designated individual to assure that devices and labeling materials from prior operations do not remain in the labeling or packaging area. Any such items found shall be destroyed, disposed of, or returned to storage prior to the onset of a new or different labeling or packaging operation.

(d) *Storage.* Labels and labeling shall be stored and maintained in a manner that provides proper identification and is designed to prevent mixups.

(e) *Labeling materials.* Labeling materials issued for devices shall be examined for identity and, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and additional processing instructions. A record of such examination, including the date and person performing the examination, shall be maintained in the device history record.

§ 820.121 Critical devices, device labeling.

In addition to the requirements of § 820.120, the following requirements apply to critical devices:

(a) *Control number.* Labels issued for critical devices shall contain a control number.

(b) *Labeling check.* The signature of the individual who proofreads the labels and other labeling, and the date of the proofreading, shall be recorded.

(c) *Access restriction.* Access to the labels and other labeling shall be restricted to authorized personnel.

§ 820.130 Device packaging.

The device package and any shipping container for a device shall be designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

Subpart H—Holding, Distribution, and Installation

§ 820.150 Distribution.

There shall be written procedures for warehouse control and distribution of finished devices to assure that only those devices approved for release are distributed. Where a device's fitness for use or quality deteriorates over time, there shall be a system to assure that the oldest approved devices are distributed first.

§ 820.151 Critical devices, distribution records.

In addition to the requirements of § 820.150, adequate distribution records for critical devices shall include, or make reference to the location of: the name and address of the consignee, the name and quantity of devices, the date shipped, and the control number used. These records shall be retained as required by § 820.180(b).